FEB - 3 2014

TERUMO
Cardiovascular Systems

K133151

SECTION 5 – 510(K) SUMMARY
Sarns™ High-Flow Aortic Arch Cannula

Date Prepared:	September 2013
Sponsor Information:	
Owner/Applicant/Submitter:	Terumo Cardiovascular Systems Corporation 6200 Jackson Road Ann Arbor, Michigan 48103 Phone: 1-800-262-3304 Fax: 410-398-6079 Registration No. 1828100
Contact Person:	Garry A. Courtney, MBA, RAC Corporate Director, Regulatory Affairs 125 Blue Ball Road Elkton, MD 21921 Phone: 1-800-262-3304 ext. 7486 Fax: 410-398-6079 Email: garry.courtney@terumomedical.com
Device Names/Classifications:	
Device Trade Name:	Sarns™ High-Flow Aortic Arch Cannula
Device Common Name:	Aortic cannula for cardiopulmonary bypass
Classification Name:	Cardiopulmonary bypass vascular catheter, cannula, tubing
Regulation Number:	21 CFR 807.4210
Classification:	Class II
Product Code:	DWF

Predicate Devices:
- Sarns™ High Flow Aortic Arch Cannula, K770429
- Sarns™ X-coated Aortic Cannula, K083301

Purpose of Submission:
Terumo Cardiovascular Systems is submitting this Premarket Notification due to cumulative changes that have been made since the time that the original submissions were cleared by FDA. Although none of the individual changes were determined to be significant, Terumo Cardiovascular Systems Corporation believes it is appropriate to submit a 510(k) that represents the devices in their current design state.

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Intended Use/Indications for Use:
The Sarns™ High-Flow Aortic Arch Cannula is indicated for perfusion of the ascending aorta during cardiopulmonary bypass surgery for up to 6 hours of use.

Principles of Operation and Technology:
The subject devices are modifications of the predicate devices, and these modifications do not impact the technology of the predicate devices, the principles of operation and do not raise different or new questions of safety and effectiveness from the predicates. The Sarns™ High-Flow Aortic Arch Cannula provides a conduit for the flow of patient blood within the extracorporeal circuit during cardiopulmonary bypass surgery. Typically, blood is gravity drained from the body into a blood reservoir. From the reservoir, blood then is propelled through the balance of the extracorporeal circuit via a roller pump or centrifugal pump. The Sarns™ High-Flow Aortic Arch Cannula is a component within the circuit that tunnels patient blood back into the body.

Design and Materials:
The design of the Sarns™ High-Flow Aortic Arch Cannula allows patient blood to re-enter the body after the blood has routed through an extracorporeal circuit for blood oxygenation. The design of the cannula is simple in that it consists of a tubular conduit with a tip that can be positioned into the patient's anatomy (ascending aorta) to allow the blood to re-enter the vascular blood stream.

The materials of construction for the Sarns™ High-Flow Aortic Arch Cannula can include polyvinylchloride, PMEA polymer, polyethylene, acrylonitrile butadiene styrene and stainless steel.

Performance Evaluations:
Clinical studies involving patients are not necessary to demonstrate the safety and effectiveness of the subject devices. Performance assessments for safety and effectiveness were accomplished through bench studies that included the following evaluations:

- force at break
- liquid and air leak
- ink adhesion
- hemolysis
- torque
- corrosion
- pressure drop

Substantial Equivalence Comparison:
The information presented in this section depicts a comparison between the subject device, the modified Sarns™ High-Flow Aortic Arch Cannula and the predicate device, the unmodified Sarns™ High-Flow Aortic Arch Cannula.

- ***Comparison of Intended Use:***
  The modified Sarns™ High-Flow Aortic Arch Cannula and the predicate Sarns™ High-Flow Aortic Arch Cannula have the exact same intended use statements:

  > The modified and the unmodified Sarns™ High-Flow Aortic Arch Cannulae are each indicated for perfusion of the ascending aorta during cardiopulmonary bypass surgery for up to 6 hours of use.

- ***Duration of Use***:
  The modified Sarns™ High-Flow Aortic Arch Cannula and the predicate Sarns™ High-Flow Aortic Arch Cannula can both be used in procedures lasting up to 6 hours in duration.

- ***Comparison of Labeling***:
  The labeling that will be used for the modified device is similar to the labeling used with the predicate device, although some labeling is revised to provide greater clarity for the user. The revised *instructions* labeling accurately presents the directions that are necessary for the end-user to employ the device in a safe and effective manner. Terumo submits that the labeling complies with applicable regulations in those regions where the device is to be distributed.

- ***Comparison of Operation and Technology:***
  The modified Sarns™ High-Flow Aortic Arch Cannula and the predicate Sarns™ High-Flow Aortic Arch Cannula utilize the exact same technologies and principles of operation. The technology of the modified Cannula is not impacted by the modifications made to the subject device.

- ***Comparison of Design:***
  With respect to the design of the modified Sarns™ High-Flow Aortic Arch Cannula, there have been no significant design changes implemented. Terumo has made *non-significant* changes since the original submission of these devices – each of which has been determined to maintain the integrity of the product without adversely impacting safety and/or performance.

- ***Comparison of Materials:***
  The materials of construction used in the modified Sarns™ High-Flow Aortic Arch Cannula are the same generic materials that are used in the predicate device with the addition of an luer cap made of ABS plastic. Both the modified Sarns™ High-Flow Aortic Arch Cannula and the predicate cannula have been demonstrated to meet biocompatibility requirements.

- ***Comparison of Performance:***
  Terumo Cardiovascular has conducted performance studies with the modified devices to ensure that they all continue to satisfy appropriate device performance specifications and to ensure that they satisfy customer needs. There are no appreciable differences between the subject devices and the predicate devices.

Conclusion:
The information and data included in the 510(k) notice demonstrate the Sarns™ High-Flow Aortic Arch Cannula is *substantially equivalent* to the predicate devices for perfusion of the ascending aorta during cardiopulmonary bypass for up to 6 hours of use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 3, 2014

Terumo Cardiovascular Systems Corporation
Garry Courtney, MBA, RAC
6200 Jackson Road
Ann Arbor, MI 48103

Re: K133151
Trade/Device Name: Sarns™ High-Flow Aortic Arch Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiovascular (74)
Regulatory Class: II
Product Code: DWF
Dated: September 27, 2013
Received: October 17, 2013

Dear Mr. Courtney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram Zuckerman, MD
Director, Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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SECTION 4 – INDICATION FOR USE
Sarns™ High-Flow Extended Aortic Arch Cannula

510(k) Number (if known): K133151 Unknown at time of submission

Device Name: Sarns™ High-Flow Aortic Arch Cannula

Indications for Use:
Device Intended Use - The device is indicated for perfusion of the ascending aorta during cardiopulmonary bypass surgery for up to six hours of use.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D) or Over-The-Counter Use _____ (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)